

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD.,)	REDACTED -
)	PUBLIC FILING
Plaintiff,)	
)	C.A. No. 21-1015 (LPS)
v.)	
)	
SAREPTA THERAPEUTICS, INC.,)	
)	
Defendant.)	

**SAREPTA’S ANSWERING BRIEF IN OPPOSITION TO
NIPPON SHINYAKU’S MOTION FOR PRELIMINARY INJUNCTION**

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Defendant Sarepta Therapeutics, Inc. (“Sarepta”) respectfully submits this Answering Brief in Opposition to Plaintiff Nippon Shinyaku Co., Ltd.’s (“Nippon Shinyaku”) Motion for Preliminary Injunction. *See* D.I. 4-5.

I. Nature and Stage of Proceedings

Sarepta and Nippon Shinyaku are competitors in developing and commercializing therapies for the treatment of Duchenne Muscular Dystrophy (“DMD”). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] on June 21, 2021, Sarepta filed petitions for *inter partes* review (“IPR”) with the Patent Trial and Appeal Board (“Board” or “PTAB”) of the USPTO, challenging the patentability of the claims of seven of Nippon Shinyaku’s patents (collectively, “the NS Patents”).¹ *See* D.I. 5 at 1. [REDACTED]

¹ *See Sarepta Therapeutics, Inc. v. Nippon Shinyaku Co., Ltd.*, IPR2021-01134 (U.S. Patent No. 9,708,361); IPR2021-01135 (U.S. Patent No. 10,385,092); IPR2021-01136 (U.S. Patent No. 10,407,461); IPR2021-01137 (U.S. Patent No. 10,487,106); IPR2021-01138 (U.S. Patent No. 10,647,741); IPR2021-01139 (U.S. Patent No. 10,662,217); IPR2021-01140 (U.S. Patent No. 10,683,322).

[REDACTED]

[REDACTED] by filing the IPR Petitions at the PTAB. *See* D.I. 5 at 4.

Nippon Shinyaku filed this action on July 13, 2021 (1) asserting that Sarepta [REDACTED] (2) alleging infringement of the NS Patents; and (3) seeking a declaratory judgment of non-infringement and invalidity with respect to certain patents licensed to Sarepta. *See* D.I. 2. Nippon Shinyaku filed its motion for a preliminary injunction [REDACTED] at the same time. *See* D.I. 4-5.

II. Summary of Argument

Nippon Shinyaku has not established any basis for grant of a preliminary injunction.

1. Likelihood of success on the merits: Nippon Shinyaku has failed to show that it is likely to succeed [REDACTED] [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] This interpretation is incorrect for several reasons.

Nippon Shinyaku's interpretation ignores the [REDACTED]

[REDACTED]

[REDACTED] *June 21, 2021*. *See* D.I. 2, Ex. A at 2, [REDACTED]. Sarepta filed its IPR petitions [REDACTED] *See* D.I. 5 at 4. Nippon Shinyaku even acknowledges that [REDACTED] June 21, 2021. *Id.* Nippon Shinyaku contends, however, that [REDACTED]

[REDACTED] *June 21, 2023*. *Id.* at 4, 6. Nippon Shinyaku's position would [REDACTED] violating a cardinal rule of contract

interpretation. *See Martin Marietta Materials, Inc. v. Vulcan Materials Co.*, 68 A.3d 1208, 1221 (Del. 2012) (applying the “cardinal rule ... that, where possible, a court should give effect to *all* contract provisions”) (citations omitted). Nippon Shinyaku fails to address [REDACTED]

Properly interpreted under Delaware law, [REDACTED]

[REDACTED] The portion of the sentence relied upon by Nippon Shinyaku refers to [REDACTED]

[REDACTED] D.I. 2, Ex. A at [REDACTED]. [REDACTED]

[REDACTED] *See, e.g.*, 28 U.S.C. § 1338 (federal district courts have original jurisdiction over any civil action “arising under” any Act of Congress relating to patents). Similarly, [REDACTED]

[REDACTED] D.I. 2, Ex. A at [REDACTED]. This again refers to [REDACTED]

[REDACTED] Thus, when read in context, [REDACTED]

In essence, Nippon Shinyaku is asking this Court to find that Sarepta [REDACTED]

[REDACTED] Moreover, nothing [REDACTED]

[REDACTED] To the contrary, the parties [REDACTED]

[REDACTED] For example, [REDACTED]

[REDACTED]

[REDACTED] *See* D.I. 2, Ex. A at [REDACTED]. In addition, the [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] *Id.* at 2, [REDACTED]. The parties also [REDACTED]

[REDACTED]

Id. at 2, [REDACTED]. Nothing [REDACTED]

[REDACTED]

See 35 U.S.C. § 315(b).

2. Irreparable harm: Nippon Shinyaku has also failed to show that it will suffer any irreparable harm in the absence of a preliminary injunction. Because Sarepta did not [REDACTED] [REDACTED] [REDACTED] Nippon Shinyaku cannot be irreparably harmed if those petitions are allowed to proceed. The America Invents Act (“AIA”) expressly contemplates that IPR proceedings may run concurrently with district court patent infringement actions. *See id.* Moreover, Nippon Shinyaku’s concerns about possible inconsistent rulings or duplicative proceedings, caused by its own filing of this action, do not establish irreparable harm in view of the availability of a stay of this proceeding. *See* D.I. 5 at 7-9.

3. Balance of the equities: Nippon Shinyaku has also failed to show that the balance of equities tilts in its favor. Under the AIA, Sarepta must file any IPR petitions within one year of being served with an infringement complaint, i.e., by July 14, 2022. *See* 35 U.S.C. § 315(b); D.I. 9. After triggering the one-year IPR deadline through the filing of this action, however, Nippon Shinyaku is now asking the Court to order Sarepta to withdraw its IPR petitions until June 21, 2023. D.I. 5 at 6. Thus, Nippon Shinyaku’s injunction request, if granted, would preclude Sarepta

from pursuing any IPR petitions at all, as they would be time-barred under § 315(b). Consequently, Sarepta would be severely harmed by entry of a preliminary injunction.

By contrast, Nippon Shinyaku would suffer no undue burden or harm if Sarepta's IPR petitions are not withdrawn. The IPR petitions are authorized by statute, and a stay of this litigation to address any duplicative adjudication of the patentability issues remains available. Moreover, Nippon Shinyaku created the risk of duplicative adjudication by filing this action after Sarepta filed its IPR petitions.

4. Public interest: Nippon Shinyaku has also failed to show that the public interest favors issuance of a preliminary injunction. The absence of any [REDACTED] eliminates any public interest support for an injunction. Further, as embodied in the AIA, strong federal policies favor challenging patents that fail to meet the statutory requirements for patentability. The issuance of a preliminary injunction would disserve the public interest by eliminating Sarepta's ability to challenge the patentability of Nippon Shinyaku's patents before the Board.

III. Counterstatement of Facts

A. Duchenne Muscular Dystrophy ("DMD")

DMD is a rare genetic disorder characterized by progressive muscle deterioration and weakness. *See* "FDA grants accelerated approval to first targeted treatment for rare Duchenne muscular dystrophy mutation," FDA News Release (Dec. 12, 2019).² It is the most common type of muscular dystrophy. *Id.* DMD is caused by an absence of dystrophin, a protein that helps keep muscle cells intact. *Id.* The first symptoms are usually seen between three and five years of age and worsen over time. *Id.* The disease often occurs in people without a known family history of

² *See* <https://www.fda.gov/news-events/press-announcements/fda-grants-accelerated-approval-first-targeted-treatment-rare-duchenne-muscular-dystrophy-mutation> (last accessed August 10, 2021).

the condition and primarily affects boys, but in rare cases it can affect girls. *Id.* DMD occurs in about one out of every 3,600 male infants worldwide. *Id.*

Patients with DMD progressively lose the ability to perform everyday activities independently and often require a wheelchair and assistance by their early teens. *Id.* As the disease progresses, life-threatening heart and respiratory conditions can occur. *Id.* Patients typically die of the disease in their 20s or 30s, although disease severity and life expectancy vary. *Id.*

B. Sarepta's Development of Vyondys 53[®]

On December 12, 2019, the U.S. Food and Drug Administration ("FDA") granted accelerated approval of Sarepta's Vyondys 53[®] (golodirsen) injection to treat DMD patients who have a confirmed mutation of the dystrophin gene that is amenable to exon 53 skipping. *Id.* About 8% of patients with DMD have this mutation. *Id.* Vyondys 53 was the first-available treatment targeted specifically for patients amenable to exon 53 skipping. *Id.* Nippon Shinyaku's Viltepso[®] (viltolarsen) injection was approved on August 12, 2020, as the second FDA-approved targeted treatment for patients amenable to exon 53 skipping.³ *See* D.I. 5 at 2.

C. [REDACTED]

On [REDACTED], [REDACTED]

[REDACTED]

[REDACTED] *See* D.I. 2, Ex. A at 1, 2 [REDACTED]

[REDACTED].

[REDACTED]

[REDACTED]

[REDACTED]

³ *See* <https://www.fda.gov/news-events/press-announcements/fda-approves-targeted-treatment-rare-duchenne-muscular-dystrophy-mutation> (last accessed August 10, 2021).

[REDACTED]

D.I. 2, Ex. A at [REDACTED] (emphases added).

Thus, [REDACTED]

[REDACTED]

[REDACTED] *See id.; id.* at 2 [REDACTED]

id. at [REDACTED]. Nippon Shinyaku acknowledges that because the [REDACTED]

[REDACTED]

[REDACTED] *See* D.I. 5 at 4.

D. Sarepta's Timely Filing of IPR Petitions [REDACTED]

In accordance with [REDACTED]

[REDACTED] Sarepta filed seven IPR petitions with the Board, challenging the patentability of certain NS Patents. *See* D.I. 5 at 1. Those petitions remain pending and have been assigned the following case numbers: IPR2021-01134; IPR2021-01135; IPR2021-01136; IPR2021-01137; IPR2021-01138; IPR2021-01139; and IPR2021-01140. *Id.*

On June 24, 2021, outside counsel for Nippon Shinyaku wrote Sarepta, asserting that Sarepta had [REDACTED] [REDACTED]

[REDACTED]

[REDACTED] Sarepta responded

on June 30, 2021, disputing [REDACTED]. *See* Ex. 2. Sarepta explained why there was [REDACTED]

pointing out, for example,

[REDACTED] *Id.* Nippon Shinyaku did not respond to Sarepta's letter. Instead, two weeks later, it filed this action alleging, *inter alia*, that Sarepta had [REDACTED] [REDACTED]

See D.I. 2.

IV. Nippon Shinyaku Is Not Entitled to a Preliminary Injunction

A. Standard for a Preliminary Injunction

“[A] preliminary injunction is an ‘*extraordinary* remedy never awarded as of right.’” *Benisek v. Lamone*, 138 S. Ct. 1942, 1943 (2018) (per curiam) (citation omitted) (emphasis added).

The party seeking a preliminary injunction must establish that it is likely to succeed on the merits of its claim; that it is likely to suffer irreparable harm in the absence of preliminary relief; that the balance of equities weighs in its favor; and that an injunction serves the public’s interest. *See Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008).

Where, as here, Nippon Shinyaku seeks a mandatory injunction commanding some positive act (i.e., ordering Sarepta to withdraw its IPR petitions), its burden is “particularly heavy” and its right to relief must be “indisputably clear.” *Doe v. Del. State Univ. Bd. of Trs.*, No. 20-1559 (MN), 2021 WL 2036670, at *2 (D. Del. May 21, 2021) (citations omitted). As explained below, Nippon Shinyaku fails to establish any “indisputably clear” [REDACTED].

B. Delaware Law Governing Contracts

Delaware law governs the [REDACTED]. *See* D.I. 2, Ex. A at [REDACTED]. Under Delaware law, construction of contract language is a question of law. *See Cordis Corp. v. Boston Scientific Corp.*, 868 F. Supp. 2d 342, 351 (D. Del. 2012). In interpreting a contract, the court’s goal is to determine the shared intent of the parties. *See Sassano v. CIBC World Markets Corp.*, 948 A.2d 453, 462 (Del. Ch. 2008). Delaware courts adhere to the “objective theory” of contract interpretation. *Id.* Accordingly, “the court looks to the most objective indicia of that intent: the words found in the

written instrument.” *Id.* The primary consideration in interpreting a contract is to “attempt to fulfill, to the extent possible, the reasonable shared expectations of the parties at the time they contracted.” *Comrie v. Enterasys Networks, Inc.*, 837 A.2d 1, 13 (Del. Ch. 2003) (citation omitted); *Rhone-Poulenc Basic Chems. Co. v. Am. Motorists Ins. Co.*, 616 A.2d 1192, 1195 (Del. 1992).

Interpreting a contract under Delaware law requires consideration of the contract as a whole without reliance “on any single passage in isolation.” *O’Brien v. Progressive N. Ins. Co.*, 785 A.2d 281, 287 (Del. 2001). A court must give effect to all contract terms and read the agreement in a way that, if possible, reconciles all of its provisions. *See Alta Berkeley VI C.V. v. Omneon, Inc.*, 41 A.3d 381, 385-86 (Del. 2012); *Martin Marietta Materials*, 68 A.3d at 1221 (applying the “cardinal rule ... that, where possible, a court should give effect to *all* contract provisions”) (citations omitted). The court’s interpretation should “not render any provisions ‘illusory or meaningless.’” *O’Brien*, 785 A.2d at 287 (citation omitted).

C. Nippon Shinyaku Cannot Establish [REDACTED]

Nippon Shinyaku has failed to show that a preliminary injunction should be granted. It does not allege any [REDACTED]
Nor does it address [REDACTED]

[REDACTED] Instead, Nippon Shinyaku bases its motion solely on [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

D.I. 2, Ex. A at [REDACTED] (emphasis added).

Nippon Shinyaku asserts that, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] D.I. 5 at 6-7. This interpretation is incorrect for several reasons.

1. Nippon Shinyaku's Interpretation [REDACTED]

Under [REDACTED]

[REDACTED]

[REDACTED] See D.I. 2, Ex. A at [REDACTED]; *id.* at 2

[REDACTED]; *id.* at [REDACTED]

Because [REDACTED]'s effective date was [REDACTED]

[REDACTED] [REDACTED]. See D.I. 5 at 4. [REDACTED]

[REDACTED] *Id.* Under Nippon Shinyaku's interpretation of [REDACTED]

[REDACTED]

[REDACTED] *Id.* at 6-7. Nippon Shinyaku's position would therefore [REDACTED]

[REDACTED]

Nippon Shinyaku's interpretation of [REDACTED] violates the "cardinal rule ... that, where possible, a court should give effect to *all* contract provisions." *Martin Marietta Materials*, 68 A.3d at 1221 (citations omitted); *see also Priority Healthcare Corp. v. Aetna Specialty Pharmacy, LLC*, 590 F. Supp. 2d 663, 668 (D. Del. 2008) (adopting a "harmonious construction" of two sections of an agreement based on "the basic principle of contract interpretation—that a contract should not be read so as to render any terms or provisions meaningless") (citing 11 *Williston on Contracts* § 32:5 (4th ed.) ("An interpretation which gives effect to all

provisions of the contract is preferred to one which renders a portion of the writing superfluous, useless or inexplicable. A court will interpret a contract in a manner that gives reasonable meaning to all of its provisions, if possible.”)).

The Court should therefore reject Nippon Shinyaku’s incorrect interpretation, which would [REDACTED] *See id.*; *see also Dow Chem. Canada Inc. v. HRD Corp.*, 909 F. Supp. 2d 340, 344-45 (D. Del. 2012) (“Courts must strive to give effect to all provisions of a contract and not render any provision meaningless.”), *aff’d*, 587 F. App’x 741 (3d Cir. 2014). Nippon Shinyaku fails to address [REDACTED] [REDACTED] D.I. 5 at 6-7. It does not explain, for example, why its broad reading of [REDACTED] [REDACTED]

As explained below, under a proper reading of [REDACTED] [REDACTED] [REDACTED]

2. [REDACTED]

Nippon Shinyaku ignores the context [REDACTED]

[REDACTED] *See id.*; D.I. 2, Ex. A at [REDACTED]. As the context shows, [REDACTED] [REDACTED]

a. [REDACTED]

The sentence [REDACTED]

[REDACTED] D.I. 2, Ex. A at [REDACTED]. This phrase [REDACTED] [REDACTED]

Compare 28 U.S.C. § 1338 (federal district courts have original jurisdiction over any civil action “arising under” any Act of Congress relating to patents), *with* 35 U.S.C. § 311 (a petitioner may request to cancel as unpatentable one or more claims of a patent only on grounds raised under §§ 102 or 103).

Article III of the Constitution, which provides that federal courts can hear “all cases, in law and equity, *arising under* this Constitution, [and] *the laws of the United States*.” U.S. Const. Art. III, Sec. 2 (emphasis added). Similarly, 28 U.S.C. § 1331 provides that district courts have original jurisdiction over all civil actions “arising under” the laws of the United States. 28 U.S.C. § 1331; *see also* *Gunn v. Minton*, 568 U.S. 251, 257 (2013) (discussing district court jurisdiction under Sections 1331 and 1338(a)).

b.

The sentence cited by Nippon Shinyaku also states

See, e.g., Path to Riches, LLC v. CardioLync, Inc., 290 F. Supp. 3d 280, 285 (D. Del. 2018) (describing the federal court doctrine of *forum non conveniens*) (citing *Sinochem Int’l Co. v. Malaysia Int’l Shipping Corp.*, 549 U.S. 422, 425 (2007)). In addition,

D.I. 2, Ex. A at . Nippon Shinyaku simply disregards these portions of the sentence it cites. *See* D.I. 5 at 6-7.

Notably, the heading

See Cantor Fitzgerald, L.P. v. Cantor, 724 A.2d 571, 581 n.35 (Del. Ch. 1998) (“Although contract headings are not controlling

evidence of the meaning of a contract's substantive provisions, they may be considered as additional evidence tending to support the substantive provisions.").

Thus, in context, [REDACTED]

[REDACTED] See D.I. 2,
Ex. A at [REDACTED]; *id.* at [REDACTED].

By contrast, [REDACTED]

[REDACTED] IPR petitions are filed with the Board and nowhere else. *See* 35 U.S.C. § 316(c). Any person who is not the patent owner can file an IPR petition with the Board. *Id.* at § 311(a). Upon filing of an IPR petition, the petitioner serves a copy of the petition and supporting evidence on the patent owner at the correspondence address of record for the challenged patent. *See* 37 C.F.R. § 42.105. It does not matter for an IPR petition filing whether the patent owner is a foreign or domestic company. *See id.* And, as discussed above, IPR proceedings cannot be transferred. 35 U.S.C. § 316(c). Moreover, even if the parties wanted to, they could not have consented to adjudicate future IPR proceedings in this Court (or any other district court) where no such jurisdiction exists. *See Epic/Freedom, LLC v. Aveanna Healthcare, LLC*, No. 2020-0908-JRS, 2021 WL 1049469, at *2 n.14 (Del. Ch. Mar. 19, 2021) ("[T]he parties cannot contract for jurisdiction where it otherwise is unavailable.").

3. [REDACTED]

In essence, Nippon Shinyaku is asking this Court to find that Sarepta [REDACTED]

[REDACTED] A waiver of statutory rights, however, should not be inferred unless it is clear and unambiguous; silence cannot suffice. *See, e.g., Kortum v. Webasto Sunroofs, Inc.*, 769 A.2d 113, 125 (Del. Ch. 2000) (“There can be no waiver of a statutory right unless that waiver is clearly and affirmatively expressed in the relevant document.”).

Here, [REDACTED]

[REDACTED] To the contrary, the parties [REDACTED]

[REDACTED] For example, [REDACTED]

[REDACTED]. *See* D.I. 2, Ex. A at [REDACTED]. In addition, [REDACTED]

[REDACTED] *See* D.I. 2,

Ex. A at 2 [REDACTED], [REDACTED]. In fact, [REDACTED]

[REDACTED] *See* Ex. 3

(Sarepta’s opposition to EP 3018211B1) at 3. The parties further [REDACTED]

[REDACTED] *See* D.I. 2, Ex. A at 2, [REDACTED]. Nothing in the [REDACTED]

[REDACTED] *See* 35 U.S.C. § 315(b).

4. Nippon Shinyaku's Cited Cases Are Inapposite

Nippon Shinyaku cites two non-controlling cases granting injunctions based on patent license agreements interpreted under California law. *See* D.I. 5 at 10 (citing *Dodocase VR, Inc. v. MerchSource, LLC*, 767 F. App'x 930 (Fed. Cir. 2019), and *Nomadix, Inc. v. Guest-Tek Interactive Ent., Ltd.*, No. 2:19-cv-04980, 2020 WL 1939826 (C.D. Cal. Apr. 22, 2020)). Nippon Shinyaku makes no effort to show that these cases apply here. They do not.

The patent license agreements at issue in those cases were materially different than the [REDACTED] *First*, unlike the license agreements at issue in *Dodocase* and *Nomadix*, [REDACTED]

[REDACTED] *See* D.I. 2, Ex. A at [REDACTED]. The [REDACTED]

[REDACTED]

[REDACTED] *Id.* [REDACTED]

[REDACTED] *Id.* at [REDACTED]. Neither of the license agreements at issue in *Dodocase* and *Nomadix* contained [REDACTED]

[REDACTED]

[REDACTED]

Second, the license agreements at issue in *Dodocase* and *Nomadix* contained a grant of intellectual property rights. *See Dodocase VR, Inc. v. MerchSource, LLC*, No. 17-cv-07088, 2018 WL 1475289, at *1 (N.D. Cal. Mar. 26, 2018); *Nomadix, Inc. v. Guest-Tek Interactive Entm't Ltd.*, No. 2:19-cv-04980-AB, 2020 WL 1032395, at *1 (C.D. Cal. Jan. 23, 2020). Here, the [REDACTED]

[REDACTED] *See* D.I. 2, Ex. A at [REDACTED]. Unlike the license agreements at issue in *Dodocase* and *Nomadix*, the instant [REDACTED]

[REDACTED]

The district court in *Kannuu Pty Ltd. v. Samsung Elecs. Co.*, 2021 WL 195163, at *4-5 (S.D.N.Y. Jan. 19, 2021), relied on [REDACTED] in denying the patentee's motion to enjoin IPR proceedings. *Kannuu*, 2021 WL 195163, at *4-5 (noting the confidentiality agreement at issue there "implicate[d] confidentiality and not the intellectual property rights of the parties."); *id.* at *5 (holding that "IPR proceedings concern the validity of patents, not confidentiality."). The court in *Kannuu* thus found that the IPR proceedings "d[id] not 'relat[e] to' the Agreement or transactions contemplated under it, and thus d[id] not fall within the scope of the forum selection clause." *Id.* at *5; *see also NuCurrent Inc. v. Samsung Elecs. Co.*, 2019 WL 2776950, at *5 (S.D.N.Y. July 2, 2019) (denying motion for preliminary injunction seeking withdrawal of IPR petitions based on forum selection clause in confidentiality agreement).

It would be illogical to construe [REDACTED]

[REDACTED] Indeed, [REDACTED]

[REDACTED] In sum, Nippon Shinyaku cannot show a likelihood of success on the merits of its [REDACTED] claim.

D. Nippon Shinyaku Would Suffer No Irreparable Harm [REDACTED]

Nippon Shinyaku has also failed to show any irreparable harm in the absence of a preliminary injunction. Nippon Shinyaku argues that it will be irreparably harmed if an injunction does not issue, as it will allegedly be deprived of [REDACTED] [REDACTED] *See* D.I. 5 at 8-9. As established above, however, [REDACTED]

[REDACTED]

[REDACTED] *Id.* Because Nippon Shinyaku cannot establish a [REDACTED], it cannot show irreparable harm by the denial of a preliminary injunction.

Further, Nippon Shinyaku's filing of this action in this Court, which includes claims for patent infringement and declaratory judgment of invalidity of Sarepta's patents, demonstrates that it has not been deprived of [REDACTED]. The possibility of a stay of this action is not tantamount to a loss of forum, and nothing [REDACTED]

[REDACTED]

Nippon Shinyaku's reliance on the unpublished decisions in *BE & K Engineering* and *ASDC Holdings* to support its allegation of irreparable harm is misplaced. *See* D.I. 5 at 8. In each of those cases, the forum selection clause conveyed "exclusive" jurisdiction on the Delaware courts. *See BE & K Eng'g Co., LLC v. RockTenn CP, LLC*, 2014 WL 186835, at *1 (Del. Ch. 2014); *ASDC Holdings, LLC v. Richard J. Malouf 2008 All Smiles Grantor Retained Annuity Tr.*, 2011 WL 4552508, at *5 (Del. Ch. 2011). By contrast, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Nippon Shinyaku further argues that it will be forced to litigate the validity of its patents on multiple fronts with the possibility of inconsistent results. *See* D.I. 5 at 8-9. Nippon Shinyaku, however, has itself brought this alleged hardship with the filing of this action. Moreover, concerns about possible "inconsistent rulings or duplicative proceedings ... do not rise to the level of irreparable harm, especially in light of the fact that the parties can ... ask[] for a stay in this

proceeding.” *Kannuu*, 2021 WL 195163, at *5 (denying motion for preliminary injunction seeking to enjoin a party from pursuing IPR petitions based on a forum selection clause in a non-disclosure agreement). In addition, the “cancellation of an improvidently issued patent is not the sort of injury that weighs in favor of [an] injunction request.” *NuCurrent*, 2019 WL 2776950, at *5 (denying motion for preliminary injunction seeking withdrawal of IPR petitions based on forum selection clause). Thus, Nippon Shinyaku will suffer no irreparable harm if an injunction does not issue, and any potential harm could be mitigated by a stay of this proceeding. On the other hand, as explained below, Sarepta would be irreparably harmed if an injunction were entered because it would be permanently deprived of its statutory right to pursue IPR challenges to the NS Patents.

E. The Balance of Equities Does Not Favor an Injunction

Nippon Shinyaku has also failed to show that the balance of equities warrants an injunction. As explained above, Sarepta timely filed its IPR petitions on June 21, 2021, [REDACTED]. [REDACTED] See D.I. 5 at 4. Nippon Shinyaku then responded by filing this patent infringement action on the same patents three weeks later. See D.I. 2. Under the AIA, defendants such as Sarepta must file any IPR petitions with the Board within one year of being served with an infringement complaint. See 35 U.S.C. § 315(b) (“An inter partes review may not be instituted if the petition requesting the proceeding is filed more than 1 year after the date on which the petitioner ... is served with a complaint alleging infringement of the patent.”). Because Nippon Shinyaku served an infringement complaint on July 14, 2021, the statutory deadline for IPR petition filings is July 14, 2022. See D.I. 9. Nippon Shinyaku, however, is asking the Court to order Sarepta to withdraw its IPR petitions [REDACTED]. [REDACTED] See D.I. 5 at 6. Nippon Shinyaku fails to acknowledge that its injunction request, if granted, [REDACTED] as they would be time-barred under § 315(b).

[REDACTED]

[REDACTED] Nippon Shinyaku's position, if adopted, would leave Sarepta [REDACTED]

[REDACTED] Such an interpretation makes no sense because, as detailed above, [REDACTED]

[REDACTED]

[REDACTED]

Therefore, Sarepta (not Nippon Shinyaku) would be severely and permanently harmed by the grant of a preliminary injunction. *See NuCurrent*, 2019 WL 2776950, at *5 (holding that in view of the one-year window for filing an IPR petition after service of a patent infringement claim, the “issuance of a preliminary injunction would likely bar Samsung from pursuing relief before the PTAB at all”); *Kannuu*, 2021 WL 195163, at *6 (“the issuance of a preliminary injunction would likely bar Samsung from pursuing relief before the PTAB at all, foreclosing a proceeding that Congress explicitly permitted”).

By contrast, Nippon Shinyaku would suffer no undue burden or harm if it is required to respond to Sarepta's IPR petitions, which are authorized by statute and were timely filed [REDACTED]

[REDACTED] To the extent Nippon Shinyaku is burdened at all, it may seek or not oppose a stay of this litigation. *See Kannuu*, 2021 WL 195163, at *6 (“Kannuu suffers from no hardship beyond simply litigating the patent validity in two fora—a situation that can be remedied by requesting a stay in one of the proceedings, as here.”).

F. The Public Interest Does Not Support Granting an Injunction

Nippon Shinyaku has also failed to show that the public interest favors an injunction. As explained above, [REDACTED]

[REDACTED] The absence of any [REDACTED] eliminates any public interest support for

an injunction. *See id.* (“Because the instant forum selection clause is inapplicable, the public interest favors allowing Samsung to litigate the validity of the patents at issue before the PTAB.”).

Moreover, strong public policies favor permitting post-grant challenges to patents that fail to meet the statutory requirements for patentability, such as the NS Patents, rather than engaging in lengthy and costly litigation in district court. *See, e.g., Cuozzo Speed Technologies, LLC v. Lee*, 136 S. Ct. 2131, 2135 (2016) (“The purpose of inter partes review is . . . to protect the public’s ‘paramount interest in seeing that patent monopolies . . . are kept within their legitimate scope.’”); *see also Lear, Inc. v. Adkins*, 395 U.S. 653, 674 (1969) (discussing the “strong federal policy favoring the full and free use of ideas in the public domain”). Congress enacted the AIA in response to a “growing sense that questionable patents are too easily obtained and are too difficult to challenge.” H.R. Rep. No. 112-98(I), at 39 (2011). A key purpose of the AIA—and the IPR proceedings it established—was to provide “a more efficient system for challenging patents that should not have issued.” *Id.* at 39-40.

In view of these important public interests, which are embodied in the AIA, enjoining Sarepta from exercising its statutory right to pursue IPRs would thwart congressional intent and disserve the public’s interest by unfairly eliminating Sarepta’s ability to resolve the unpatentability of Nippon Shinyaku’s patent claims before the Board. *See NuCurrent*, 2019 WL 2776950, at *6 (grant of a preliminary injunction “would eliminate Samsung’s ability to litigate the validity of those same patents before the PTAB, which offers unique procedural benefits to patent litigants”).

V. Conclusion

Nippon Shinyaku has failed to meet its “particularly heavy” burden to establish an “indisputably clear” right to relief in this case. *Doe v. Del. State Univ. Bd. of Trs.*, 2021 WL 2036670, at *2. The Court should deny Nippon Shinyaku’s motion for preliminary injunction.

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CERTIFICATE OF SERVICE

I hereby certify that on August 11, 2021, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on August 11, 2021, upon the following in the manner indicated:

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